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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,710	05/16/2001	Franciscus Bernardus Gemma Benneker	POT-010US3	9651

34610 7590 02/25/2003

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/855,710

Applicant(s)
Benneker et al.

Examiner
Celia Chang

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1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 9, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24, 25, and 27-29 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. A response filed by applicants in Paper no. 8, dated Dec. 9, 2002 has been entered. No amendments were made. Claims 24-29 are pending.

2. The rejection of claims 27-29 under 35 USC 102(b) over Barnes et al. '723 or 102(e) over Ward et al. '132 are maintained for reason of record.

Applicants argument with respect to Craig et al. '927 is irrelevant since each application should be evaluated on its own merit. When an allowable claim is found, then, an assessment of whether two parties are claiming the "same" invention to warrant declaration of interference.

In the instant case, it is noted that while the broad claims 27-29 are anticipated by prior art Barnes '723 or Ward et al. '132, there is insufficient evidence to warrant "identical products" of the instant claims with the products of Craig et al. '927. It is well recognized that anhydrous, hemihydrates or solvates of paroxetine salt are different products (see Ward '132 columns 4-5). The product that will be obtained will be affected by the particular choice of solvents in crystal formation. While species anticipating the claims rendered the claims rejectable, the specific solvents of the dependent claims employing ethylacetate evidenced that the product by process of the instant claims will be a paroxetine hydrochloride anhydrate with 0.4% ethylacetate (see example 12 Ward '132), thus, are patentably distinct from the hemihydrate exemplified by Craig et al. '927 (see examples 51-53).

3. The rejection of claims 24-25 under 35 USC 103(a) over Stemp et al. '496 in view of Barnes et al. '723 is maintained for reason of record.

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Applicants argued that conversion of paroxetine methanesulfonate to hydrochloride can produce high purity is not expected by Stemp et al. '496 is not persuasive. Initially, it is noted that "purity" of product is not a limitation of the claims. Further, it was clearly delineated that in establishing a *prima facie* case that (I) the various pharmaceutical salt, (ii) the explicit exemplification together with conventional teaching of multiple examples i.e. Barnes '723, and (iii) the reasonable expectation, i.e. the examples recited in the prior art all evidenced that such process operates in analogous manner, thus, the know how, motivation, and reasonable expectation of success are found in the prior art. The elucidation that the product being made would commend high purity is hindsight, i.e. after one skilled in the art adopted the *prima facie* obvious process to obtain the product.

4. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman, can be reached on (703) 308-4698. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7922.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

WP/Chang
Feb. 20, 2003


Celia Chang
Primary Examiner
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